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Cover Page Footnote

* Associate Dean and Professor of Public Health Law and Ethics; Director, Public Health Law and Policy Program; Director, Network for Public Health Law—Western Region Office, Sandra Day O'Connor College of Law, ASU. This manuscript is based in part on a keynote address for the Notre Dame Journal of Law, Ethics & Public Policy's symposium, Regulating Life, Disease, and Death, on Thursday, March 19, 2015. I would like to acknowledge the following individuals with the Public Health Law and Policy Program, Sandra Day O'Connor College of Law, Arizona State University (ASU) for their research and editing assistance throughout the production of this article: Greg Measer, Senior Legal Researcher and J.D. Candidate (2015); Asha Agrawal, Senior Legal Researcher and J.D. Candidate (2016); and Matt Saria, Researcher and B.S. Candidate (2016).

LEGAL MYTHS OF EBOLA PREPAREDNESS AND RESPONSE

JAMES G. HODGE, JR., JD, LL.M.*

INTRODUCTION

In March 2014, Ebola viral disease (“EVD”) emerged from several West African countries as a substantial threat to global health.¹ Through a series of core legal powers pursuant to its declaration of a public health emergency of international concern (“PHEIC”) on August 8, 2014,² the World Health Organization (“WHO”) averted a global health disaster by requiring member countries to engage in multiple public health interventions. These efficacious WHO-mandated measures included implementation of border closures to limit the spread of EVD within and outside of countries like Guinea,³ Liberia,⁴ Senegal,⁵ and Sierra Leone.⁶ Industrialized nations, including the

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1. *Outbreaks Chronology: Ebola Virus Disease*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vhf/ebola/resources/outbreak-table.html#one> (last updated Feb. 20, 2015).

2. *Statement on the 1st Meeting of the IHR Emergency Committee on the 2014 Ebola Outbreak in West Africa*, WORLD HEALTH ORG. (Aug. 8, 2014), <http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/> [hereinafter *IHR Emergency Committee Statement*].

3. Saliou Samb, *Guinea Shuts Borders with Sierra Leone, Liberia in Bid to Halt Ebola*, REUTERS (Aug. 9, 2014, 11:09 PM), <http://uk.reuters.com/article/2014/08/09/uk-health-ebola-borders-idUKKBN0G90DN20140809>.

4. Umaru Fofana, *Sierra Leone Shuts Borders, Closes Schools to Fight Ebola*, REUTERS (June 11, 2014, 8:55 PM), <http://uk.reuters.com/article/2014/06/11/us-health-ebola-leone-idUKKBN0EM2CG20140611>.

5. *Travel Restrictions, Flight Operations and Screening*, INT’L SOS, https://www.internationalsos.com/ebola/index.cfm?content_id=435& (last updated Jan. 28, 2015).

6. Ellen Johnson Sirleaf, A Special Statement by the President of the Republic of Liberia (July 27, 2014), *available at* http://www.emansion.gov.lr/doc/Special%20State%20ment%20by%20President%20Ellen%20Johnson%20Sirleaf%20-1_1.pdf.

United States, responded swiftly as well through their own emergency declarations. Resulting emergency legal powers enabled strong coordination among federal, state, and local actors to systematically identify and limit cases. Among these powers, the federal Centers for Disease Control and Prevention ("CDC") required state and local governments to follow its national guidance on quarantine and isolation procedures for persons exposed to or infected with EVD.⁷ This led to the justified quarantine of health care workers ("HCWs") returning from treating Ebola patients in West African "hot zones."⁸ In collaboration with CDC, U.S. Customs and Border Control agents screened thousands of incoming passengers at multiple domestic airports to find and contain numerous, potential cases of EVD.⁹ The Food and Drug Administration ("FDA") worked in real-time to authorize the use of an extensive array of experimental tests or drugs proven effective in identifying cases and treating EVD patients.¹⁰ These (and other) legally-supported efforts worked in unison to control the spread of EVD, mitigate its impacts, and protect the public's health.

While EVD presents a very real global health threat, none of the statements above are entirely true. As discussed in this commentary, these and other public health legal preparedness themes are more myth than reality. In actuality, WHO lacks comprehensive powers to require member states to act even during emergencies.¹¹ Border closures probably do more harm to the public's health than good.¹² The federal government never declared a national state of emergency nor did the public health system take a highly-coordinated approach in its responses. CDC did not require state and local governments to follow its quarantine and isolation guidance. Not surprisingly, many states consequently chose not to.¹³ Mandatory quarantine of HCWs coming back

7. *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html> (last updated Dec. 24, 2014).

8. Press Release, Andrew Cuomo, Governor, N.Y., Governor Andrew Cuomo and Governor Chris Christie Announce Additional Screening Protocols for Ebola at JFK and Newark Liberty International Airports (Oct. 24, 2014) (on file with the N.Y. State Governor's Press Office) [hereinafter Cuomo & Christie Press Release].

9. Lawrence O. Gostin, James G. Hodge, Jr. & Scott Burris, *Is the United States Prepared for Ebola?*, 312 J. AM. MED. ASS'N 2497, 2498 (2014).

10. *Ebola Response Updates from FDA*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/ucm410308.htm> (last updated Feb. 20, 2015).

11. Danielle Renwick & Toni Johnson, *The World Health Organization (WHO)*, COUNCIL ON FOREIGN RELATIONS (Oct. 7, 2014), <http://www.cfr.org/public-health-threats-and-pandemics/world-health-organization-/p20003> ("The organization has limited authority to enforce any of its findings or recommendations. . .").

12. S.A. Miller, *A Top Health Expert Warns Against Closing Borders to Stop Ebola*, WASH. TIMES (Oct. 6, 2014), <http://www.washingtontimes.com/news/2014/oct/6/a-top-health-expert-warns-against-closing-borders->.

13. *State Ebola Protocols*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/phlp/publications/topic/ebola.html> (last updated Jan. 6, 2015).

from West Africa was neither essential nor constitutional.¹⁴ While potentially lawful, extensive airport screenings in multiple U.S. airports did not detect many, if any, active cases of EVD.¹⁵ Although FDA approved some experimental tests and drugs for EVD, the array and actual number of approvals were very limited. Those it did approve have not been shown to be efficacious in detecting or treating EVD in every case.¹⁶

Exposing these and other myths of public health legal preparedness and response reveals some of the inherent political and societal misunderstandings about the appropriate scope and use of public health powers to stymie infectious disease threats like EVD. In the throes of a perceived infectious disease threat, the public's understanding of the powers of government can become distorted, propelled in some cases by irresponsible, misinformed media.¹⁷ Regrettably, some of these themes related to the legal roles of government seem to arise in nearly every major, modern infectious disease health threat.¹⁸ Busting these myths may help obviate this cyclical trap through implementation of effective public health legal interventions to mitigate future impacts on morbidity and mortality of infectious disease threats.

MYTH I. THE WORLD HEALTH ORGANIZATION HAS EXTENSIVE EMERGENCY PUBLIC HEALTH POWERS TO RESPOND TO INFECTIOUS DISEASE THREATS LIKE EBOLA VIRAL DISEASE

As the most prominent international organization devoted to the advancement of global health, WHO can presumably legally compel its 194 member states to adhere to best practices in public health especially during emergencies, like Ebola, when the potential for significant

14. Douwe Miedema & Fiona Ortiz, *The Nurse Thrown Into Ebola Quarantine Is Planning To Sue Over 'Unconstitutional' Detention*, BUS. INSIDER (Oct. 26, 2014, 7:14 PM), <http://www.businessinsider.com/us-nurse-plans-to-sue-over-unconstitutional-ebola-quarantine-2014-10#ixzz3OujMAaDP>.

15. Liz Szabo, *No Ebola Found in Airport Checks*, USA TODAY, Dec. 10, 2014, at 3a.

16. Alan Mozes, *Diagnosing Ebola: Why Isn't There a Rapid, Reliable Test?*, CBS NEWS (Oct. 20, 2014, 2:12 PM), <http://www.cbsnews.com/news/diagnosing-ebola-why-isnt-there-a-rapid-reliable-test/> ("[T]here is no test at all to determine Ebola infection in a person without symptoms . . . [and a] PCR test typically takes at least 24 hours to bring back results.").

17. Dan Friedman & James Warren, *Ebola Czar Ron Klain Is Still Out of Sight as N.Y., N.J. Defend Decision to Go Beyond CDC Guidelines*, NY DAILY NEWS (Oct. 27, 2014, 11:41 PM), <http://www.nydailynews.com/news/politics/ebola-czar-ron-klain-sight-cdc-issues-guidelines-article-1.1989534> ("[T]he lack of a visible leader quarterbacking the Ebola effort, coupled with the scattered, decentralized realities of the American health care system, created a confounding muddle.").

18. David P. Fidler et al., *Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law, and Ethics*, J.L. MED. & ETHICS 616, 620–21 (2007) (when exercising isolation and quarantine powers there is often "confusion about which level of government should take the lead" and controversy surrounding compulsory powers, and that novel diseases sometimes highlight gaps in "legal power to act."). See also GEORGE J. ANNAS, *WORST CASE BIOETHICS: DEATH, DISASTER, AND PUBLIC HEALTH* 188, 214, 220–24, 230–32 (2010); James G. Hodge, Jr., *The Evolution of Law in Biopreparedness*, 10 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI. 38, 43 (2012).

losses of life and disability is heightened.¹⁹ In reality, WHO lacks comprehensive, enforceable legal powers to require member states to do much of anything beyond what their leadership agrees to undertake voluntarily.²⁰ When it comes to enforcing global public health interventions, WHO cannot compel countries to act, relying instead on its the power of persuasion to influence and recommend next steps. Rather than carrying a “big stick,”²¹ WHO’s powers are more akin to waving a finger of shame at offending nations and bodies.

It is not that WHO is completely powerless. Pursuant to the International Health Regulations (“IHRs”),²² revised in 2007, WHO works collaboratively with national and regional public health agencies to avert global health threats, issue emergency guidance, and seek compliance from member nations. After WHO Director-General Margaret Chan declared a PHEIC in consultation with her Emergency Committee, WHO issued recommendations on various health measures to affected members including isolation, quarantine, and travel restrictions.²³ Failing to follow WHO guidance may result in financial consequences or other ramifications for member countries. Under “exceptional circumstances,” for example, the World Health Assembly may suspend the voting privileges and services to which members are entitled.²⁴ Collaboration between WHO and the World Trade Organization (“WTO”)²⁵ increases the potential for trade sanctions for non-compliance with international health norms.²⁶ WHO’s access to

19. See, e.g., Lena H. Sun et al., *Out of Control: How the World’s Health Organizations Failed to Stop the Ebola Disaster*, WASH. POST (Oct. 4, 2014), <http://www.washingtonpost.com/sf/national/2014/10/04/how-ebola-spaced-out-of-control/>; Mark J. Siedner & John D. Kraemer, *The Global Response to the Ebola Fever Epidemic: What Took So Long?*, PLOS BLOGS (Aug. 22, 2014), <http://blogs.plos.org/speakingofmedicine/2014/08/22/global-response-ebola-fever-epidemic-took-long/>.

20. LAWRENCE O. GOSTIN, GLOBAL HEALTH LAW 110–11 (2014) (“[D]espite the WHO’s impressive normative powers, modern international health law is remarkably thin.” Member states may opt out of “regulations enter[ed] into force for all members . . . [if they] notify the D-G . . . within a specified time.”).

21. Letter from Theodore Roosevelt, Governor, State of N.Y., to Henry L. Sprague (Jan. 26, 1900) (on file with the American Treasures of the Library of Congress), available at <http://www.loc.gov/exhibits/treasures/trm139.html> (“I have always been fond of the West African proverb: ‘Speak softly and carry a big stick; you will go far.’”).

22. World Health Organization, International Health Regulations art. 15, June 15, 2007, available at http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf.

23. *IHR Emergency Committee Statement*, *supra* note 2.

24. World Health Organization, CONST. art. VII (Oct. 2006), available at http://www.who.int/governance/eb/who_constitution_en.pdf.

25. *The WTO and the World Health Organization*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/coher_e/wto_who_e.htm (last visited Jan. 22, 2015) (Although no formal agreement exists between the organizations, WHO has “observer status” on WTO committees and councils).

26. See GOSTIN, *supra* note 20, at 271, 297 (“[WTO] decisions significantly affect global health. . . . [A]greements allow countries to restrict trade for the purposes of protecting health, while at the same time barring trade discrimination. . . . The IHR 2005 was drafted to complement WTO law”); The General Agreement on Tariffs and Trade art. XX (1947), available at http://www.wto.org/english/docs_e/legal_e/gatt47_02_e.htm (WTO members may restrict trade when “necessary to protect human, animal or plant life or health.”).

outside consultation and review²⁷ helps ensure transparency and members' accountability as incentives toward compliance.²⁸

Yet, international principles of national sovereignty prevent WHO from requiring stronger adherence to its guidance through enhanced penalties or enforcement among its members.²⁹ Amidst insufficient resources³⁰ and heavy criticism for its lax approaches to controlling infectious disease,³¹ WHO lacks the basic, fundamental powers and resources it needs to more effectively prevent global health threats like EVD. The consequences of this international void are profound.³² Thousands of deaths related to EVD could have been prevented with stronger global health governance from WHO.

MYTH II. BORDER CLOSURES ARE A LAWFUL PUBLIC HEALTH TOOL TO HELP PREVENT THE SPREAD OF EBOLA

As a public health legal tool, border closures entail varying types of prohibitions on individuals' entry into or exit from countries or regions

27. Rita-Marie A. Brady, *The Revised International Health Regulations: An Historical Overview and an Analysis of Modern Application*, 4 ABA HEALTH eSOURCE (Dec. 2007), https://www.americanbar.org/newsletter/publications/aba_health_esource_home/brady.html.

28. Polly J. Price, *Ebola and the Law in the United States: A Short Guide to Public Health Authority and Practical Limits*, EMORY LEGAL STUD. RES. PAPER NO. 14-299 1, 4–5 (Dec. 2014).

Although the [IHRs] do not include an enforcement mechanism for States which fail to comply with WHO recommendations, the potential consequences of non-compliance are themselves a powerful tool [including] . . . a tarnished international image, increased morbidity/mortality in affected populations, unilateral travel and trade restrictions by other nations, and economic and social disruption. Working with WHO to control a public health event such as Ebola can help prevent reflexive, unnecessary, and counter-productive border closings and economic disruption.

Id.

29. David P. Fidler, *Globalization, International Law, and Emerging Infectious Diseases*, 2 EMERGING INFECTIOUS DISEASES 77, 80 (1996).

The central importance of the state and its sovereignty constitutes a basic weakness in international law because international legal rules tend to reflect the compromises necessary to achieve agreement and the unwillingness of states to restrict their freedom of action through international law. . . . The alleged failure of the [IHRs] may be due to the failure of WHO member states to fulfill the duties they accepted. Neither the regulations nor WHO has any power to enforce compliance.

Id.

30. GOSTIN, *supra* note 20, at 90 ("WHO Director-General, Margret Chan, announced a \$300 million budget deficit for 2010-2011"); Stephanie Nebehay, *WHO Says Cash Crunch, Rains Could Thwart Ebola Efforts*, REUTERS AFRICA (Jan. 23, 2015, 4:28 PM), <http://af.reuters.com/article/topNews/idAFKBN0KW1RW20150123?feedType=RSS&feedName=topNews> ("WHO is set to run out of cash in mid-February, a key period as it tries to halt the deadly disease, a senior WHO official said.").

31. GOSTIN, *supra* note 20, at 113 ("WHO has eschewed norm setting, preferring scientific and technical solutions to the deep-seated problems of global health. . . . Prominent scholars have chastised the WHO for its reluctance to create binding norms").

32. *Id.* at 100, 121–26.

via land, air, or water.³³ When EVD initially threatened to enter the United States, for example, multiple federal lawmakers on Capitol Hill demanded President Obama employ closure strategies to limit its introduction.³⁴ Despite their historic, common use during infectious disease outbreaks in the past,³⁵ President Obama and WHO consistently recommended against border closures in response to Ebola.³⁶ Still, such measures have been used extensively in countries directly impacted by EVD, as well as by those seeking to prevent its importation. On June 11, 2014, Sierra Leone closed its borders with Guinea and Liberia to bolster containment efforts.³⁷ On July 27, Liberia closed all but three of its border entry points to screen travelers for EVD.³⁸ Guinea closed its borders on August 9, 2014 immediately after WHO declared a PHEIC.³⁹ Senegal closed its land borders with Guinea and air borders with Nigeria, Sierra Leone, and Liberia.⁴⁰ As of late October 2014, several countries, including Canada⁴¹ and Australia,⁴²

33. *Security Message for U.S. Citizens: Dakar (Senegal), Border Closures Due to Ebola Virus Disease*, OVERSEAS SEC. ADVISORY COUNCIL (Aug. 25, 2014), <https://www.osac.gov/pages/ContentReportDetails.aspx?cid=16206>.

34. Patricia Zengerle & Roberta Rampton, *In U.S. Congress, Republicans Step Up Demands for Ebola Travel Ban*, REUTERS (Oct. 16, 2014, 5:33 PM), <http://www.reuters.com/article/2014/10/16/us-health-ebola-usa-politics-idUSKCN0I52TE20141016> ("Republican lawmakers . . . ramp[ed] up their demands that President Barack Obama impose new restrictions on travel from countries ravaged by [Ebola].").

35. See CDC *Telebriefing on Ebola Outbreak in West Africa*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (July 28, 2014, 2:30 PM), <http://www.cdc.gov/media/releases/2014/t0728-ebola.html>; Drew Hinshaw & Betsy McKay, *West Africa Strains to Contain Ebola Virus*, WALL ST. J. (July 29, 2014, 2:45 PM), <http://online.wsj.com/articles/liberia-shuts-borders-amid-ebola-outbreak-1406568519>; *Influenza Pandemic in Australia 1918-19, Melbourne Statistics*, AUSTRALIAN POSTAL HIST. & STAT., <http://www.auspostalthistory.com/articles/1123.php> (last visited Oct. 31, 2014); Sue Chan, *China Blocks Borders Over SARS*, CBS NEWS (May 2, 2003, 4:49 PM), <http://www.cbsnews.com/news/china-blocks-borders-over-sars>; Kate Saunders, *Tibet Border with Nepal Closed to Prevent Spread of SARS*, PHAYUL.COM (Apr. 27, 2003, 10:30 AM), <http://www.phayul.com/news/article.aspx?id=4104&t=1>; Michael Wines, *The SARS Epidemic: Moscow; Russia Urges Travel Limit On Suspicion Of SARS Case*, N.Y. TIMES (May 9, 2003), <http://www.nytimes.com/2003/05/09/world/the-sars-epidemic-moscow-russia-urges-travel-limit-on-suspicion-of-sars-case.html>.

36. WORLD HEALTH ORG., TRAVEL AND TRANSPORT RISK ASSESSMENT: INTERIM GUIDANCE FOR PUBLIC HEALTH AUTHORITIES AND TRANSPORT SECTOR (2014), available at <http://www.who.int/ith/updates/20140421/en/>; *No US Travel Ban Over Ebola – Obama*, BBC NEWS (Oct. 18, 2014, 10:28 AM), <http://www.bbc.com/news/world-us-canada-29674514> ("US President Barack Obama has ruled out imposing a travel ban on Ebola-hit countries of West Africa.").

37. Fofana, *supra* note 4.

38. Sirleaf, *supra* note 6.

39. Samb, *supra* note 3.

40. *Travel Restrictions, Flight Operations and Screening*, *supra* note 5.

41. Ralph Ellis, *Canada to Stop Processing Visas from Ebola Hot Spots in West Africa*, CNN (Oct. 31, 2014, 6:05 PM), <http://www.cnn.com/2014/10/31/world/world-ebola-outbreak>.

42. Euan McKirdy, *Australia Instigates Ebola-Prompted Ban on Travel from West Africa*, CNN (Oct. 28, 2014, 3:57 PM), <http://www.cnn.com/2014/10/28/world/asia/australia-immigration-policy-ebola/>.

stopped issuing visas to persons from the regions most affected by EVD.⁴³

Temporary border closures have the potential to derail the flow of Ebola cases into a country, but they can also limit importation of HCWs,⁴⁴ food, and medical supplies to needed areas,⁴⁵ effectively cutting off impacted regions in contravention to human rights protections.⁴⁶ Without sufficient enforcement (which can be nearly impossible to assure especially between adjacent countries sharing significant land boundaries), border closures may be easily evaded and rendered useless in controlling the spread of infectious diseases.⁴⁷ Even if border closures and related flight restrictions delay the spread of infectious disease, they do not eliminate the risk of spread entirely.⁴⁸ If the objective of border closures is to stop the flow of disease to protect communities, the effect more often is merely to slow it down through measures that carry significant collateral public health harms to affected populations.

MYTH III. THE THREAT OF EBOLA CONSTITUTED A PUBLIC HEALTH EMERGENCY IN THE UNITED STATES

Judging from many Americans' initial reactions to the domestic presence of EVD in late September 2014, fueled in large part by the media, one may rightfully presume the country was in a full state of emergency. Members of Congress, state governors and legislators, and others called on President Obama and his administration to scale up EVD response efforts after the arrival of the first domestic case.⁴⁹ Presi-

43. *Travel Restrictions, Flight Operations and Screening*, *supra* note 5 (Australia, Belize, Canada, and Guyana suspended issuance of visas to individuals from Ebola-infected countries).

44. Heidi Vogt, *Travel Restrictions Hamper African Medical Staff in Ebola Fight*, WALL ST. J. (Oct. 24, 2014, 12:44 AM), <http://online.wsj.com/articles/travel-restrictions-hamper-african-medical-staff-in-ebola-fight-1414086147>.

45. Miller, *supra* note 12.

46. Marcelo Giugale, *The Economic Impact of Ebola*, WORLD POST (last updated Dec. 8, 2014 5:59 AM), http://www.huffingtonpost.com/marcelo-giugale/the-economic-impact-of-eb_b_5951458.html.

47. Tom Odula & Lynsey Chutel, *Africa Stems Ebola Via Border Closings*, LUCK, YAHOO NEWS (Oct. 17, 2014, 7:15 AM), <http://news.yahoo.com/africa-stems-ebola-via-border-closings-luck-182548855.html>; Charlotte Alter, *Liberia Closes Borders to Curb Ebola Outbreak*, TIME (July 28, 2014), <http://time.com/3046012/liberia-border-ebola/>.

48. In 2006, researchers used a large-scale epidemic simulation to examine potential intervention options to address a novel influenza outbreak in Great Britain or the United States. See Neil M. Ferguson et al., *Strategies for Mitigating an Influenza Pandemic*, 442 NATURE 448, 449 (2006). Researchers found that border restrictions, even if 99.9% effective, may delay the peak of the United States pandemic by six weeks, but would not prevent the spread entirely. *Id.* Another study examined the spread of flu following flight restrictions due to the 9/11 terrorist attacks. John S. Brownstein et al., *Empirical Evidence for the Effect of Airline Travel on Inter-Regional Influenza Spread in the United States*, 3 PLOS MED. 1826, 1826 (2006). The peak date of 2001–2002 flu season in the United States was delayed by approximately one month, an effect not seen in France where flight restrictions were not imposed. *Id.* at 1829–30, 1832.

49. Gregory Korte, *Special Report: America's Perpetual State of Emergency*, USA TODAY (Oct. 23, 2014, 9:11 AM), <http://www.usatoday.com/story/news/politics/2014/10/22/>

dent Obama responded in part by classifying the international and domestic threat of EVD as a national security priority.⁵⁰ Still, despite the declaration of a PHEIC by WHO, neither President Obama⁵¹ nor Secretary Sylvia Burwell of the U.S. Department of Health and Human Services (“DHHS”) declared a national public health emergency in response to EVD. Secretary Burwell has the legal authority to make this declaration unilaterally, although typically it is issued with presidential input and assent.⁵² Unlike her predecessor, DHHS Secretary Kathleen Sebelius, who authorized a state of public health emergency for months in response to the H1N1 influenza pandemic in 2009–2010,⁵³ Burwell has not followed a similar route.⁵⁴ Instead, she issued a very limited

president-obama-states-of-emergency/16851775/; Arlette Saenz & John Parkinson, 4 *Things Some DC Lawmakers Want Obama to Do About Ebola*, ABC NEWS (Oct. 17, 2014, 12:02 PM), <http://abcnews.go.com/blogs/politics/2014/10/4-things-some-dc-lawmakers-want-obama-to-do-about-ebola/>.

Sen. Ted Cruz, R-Texas, thinks congressional leaders should call Congress back to Washington for an emergency session to examine a temporary Ebola travel ban. “The top priority should be to protect health and safety of American citizens,” Cruz said on Fox News Thursday night. “We need to do more, we’re not doing enough. If the president won’t act, then Congress should reconvene and Congress should act to protect the American people.”

Id.

50. See, e.g., Gregg Jarrett, *If Obama Thinks Ebola is a ‘National Security Priority,’ Why No Travel Ban?*, FOX NEWS (Oct. 3, 2014), <http://www.foxnews.com/opinion/2014/10/03/if-obama-thinks-ebola-is-national-security-priority-why-no-travel-ban/>. (“President Obama declared the Ebola outbreak a ‘national security priority.’ That was three weeks ago. Yet, he has failed to treat it as such.”); Connor Adams Sheets, *Obama: Ebola Outbreak A ‘National Security Threat’ With ‘Low Margin For Error’*, INT’L BUS. TIMES (Oct. 15, 2014, 6:27 PM), <http://www.ibtimes.com/obama-ebola-outbreak-national-security-threat-low-margin-error-video-1705773>.

President Barack Obama said that the Ebola outbreak is a “national security threat” with “low margin for error” during extended remarks. . . . [Additionally the President noted that] “it is very important for us to make sure that we are treating this the same way that we would treat any other significant national security threat . . . [a]nd that’s why we’ve got an all-hands-on-deck approach — from [the Department of Defense] to public health to our development assistance, our science teams — everybody is putting in time and effort to make sure that we are addressing this as aggressively as possible.”

Id.

51. Press Briefing, James S. Brady, Office of the Press Sec’y, The White House, Press Briefing by Press Secretary Josh Earnest (Oct. 16, 2014, 1:08 PM), *available at* <http://www.whitehouse.gov/the-press-office/2014/10/16/press-briefing-press-secretary-josh-earnest-10162014> (President Obama is not “actively considering [a national health emergency] right now.”); Korte, *supra* note 49 (Though he would not rule out the possibility of an emergency declaration in the future, White House Press Secretary Josh Earnest stated that it is “not something that we’re actively considering right now.”).

52. James G. Hodge, Jr. & Evan D. Anderson, *Principles and Practice of Legal Triage during Public Health Emergencies*, 64 N.Y.U. ANN. SURV. AM. L. 249, 259 (2008).

53. 2009 H1N1 Flu Outbreak: Determination that a Public Health Emergency Exists, PUB. HEALTH EMERGENCY, <http://www.phe.gov/emergency/news/healthactions/phe/Pages/h1n1.aspx> (last updated Mar. 22, 2010).

54. Press Briefing, *supra* note 51.

We’ve had senior officials like Secretary Burwell . . . talk about these kinds of facts [about Ebola]. [A] full understanding of the risk will help people understand why this is something they don’t need to be concerned about. [T]he proper way to meet that concern or to address that concern is to make sure they

declaration on December 9, 2014, under the Public Readiness and Emergency Preparedness (“PREP”) Act,⁵⁵ in support of the development of Ebola vaccines.⁵⁶

DHHS’ failure to declare a public health emergency in response to EVD is curious, but also legally defensible. It is curious because Ebola, like H1N1, is a highly-infectious, killer virus that garnered significant national attention as initial cases arose in the U.S. Unlike the airborne H1N1 flu virus, however, EVD spreads considerably less easily. However, EVD is contagious and lethal even with the availability of modern isolation units and round-the-clock health care services for patients.⁵⁷ These epidemiologic facts would seem to support a declaration of a national state of public health emergency from the moment known cases of EVD arose in the States. Similar emergencies have been declared for supposedly lesser threats, including waterborne outbreaks⁵⁸ and severe storms.⁵⁹ Why was it not declared in this case?

First, public health emergency declarations are typically based on known or imminent threats of substantial harms to the population.⁶⁰ A handful of domestic cases of a non-airborne, slowly-spreading condition like EVD does not constitute an imminent threat to the larger population’s health. Very few cases of EVD arose domestically, and only two people have died in the U.S. from EVD as of January 30, 2015.⁶¹ More people may be at risk of death from measles in the United States from the recent Disneyland outbreak in December 2014 than EVD.⁶² Sec-

have a full accounting of the facts. I’m not aware of any consideration that currently is underway [related] to the Stafford Act or any sort of national medical emergency.

Id.

55. Public Readiness and Emergency Preparedness (“PREP”) Act, Pub. L. No. 109-148, 119 Stat. 2818 (codified at Public Health Service Act, 42 U.S.C. §§ 247d-6d, 247d-6e).

56. Press Release, Sylvia M. Burwell, Sec’y, Dep’t of Health & Hum. Serv., Secretary Burwell Issues Declaration under PREP Act to Support Development of Ebola Vaccines (Dec. 9, 2014), available at <http://www.hhs.gov/news/press/2014pres/12/20141209a.html>.

57. *Ebola Spreads Slower, Kills More Than Other Diseases*, WASH. POST (Oct. 14, 2014), <http://www.washingtonpost.com/wp-srv/special/health/how-ebola-spreads/> (showing that one person infected with influenza will pass the virus on to 2–6 people while a patient infected with Ebola will, on average, only pass the virus on to 1.5–2 people).

58. Colo. Exec. Order No. D 006 08 (Mar. 21, 2008), <http://www.colorado.gov/cs/Satellite?blobcol=urldata&blobheader=application%2Fpdf&blobkey=id&blobtable=MungoBlobs&blobwhere=1228626288626&ssbinary=true>.

59. Press Release, Mike Leavitt, Sec’y, U.S. Dep’t of Health & Hum. Serv., HHS Secretary Declares Public Health Emergency for Louisiana, Texas, Mississippi, and Alabama (Aug. 31, 2008) (on file with DHHS).

60. Hodge & Anderson, *supra* note 52.

61. Lena H. Sun & Brady Dennis, *Death of Second Ebola Patient in U.S. Shows Need for Early, Accurate Tests, Experts Say*, WASH. POST (Nov. 17, 2014), http://www.washingtonpost.com/national/health-science/death-of-second-ebola-patient-in-us-shows-need-for-early-accurate-tests-experts-say/2014/11/17/b114_07_a0-6e84-11e4-893f-86bd390a3340_story.html.

62. Rosanna Xia, *California Measles Outbreak is Up to 87 Cases in 7 States, Mexico*, L.A. TIMES (Jan. 26, 2015, 5:14 PM), <http://www.latimes.com/local/lanow/la-me-ln-california-measles-outbreak-87-cases-20150126-story.html> (documenting the recent Disney measles outbreak has infected 86 people in the U.S., and one person in Mexico); Liz Szabo, *Dis-*

ond, neither DHHS nor most states (only Connecticut declared a state of public health emergency)⁶³ needed to issue any declaration to implement a plethora of routine public health powers (e.g., education, testing, screening, treatment, quarantine, isolation, closures) to address existing threats of EVD. Absent additional implications of EVD related to resource limitations, DHHS and its subsidiary agencies like CDC, FDA, and the National Institutes of Health can still respond legally. Despite calls for greater national focus on EVD and President Obama's short-lived naming of an internal "Ebola Czar" Ron Klain in October 2014,⁶⁴ federal, state, and local public health authorities decided appropriately against issuing formal emergency declarations. The perception of EVD as constituting a domestic emergency is fiction; the truth is that public health agencies and officials routinely handle threats like these across the country.

MYTH IV. THE UNITED STATES PUBLIC HEALTH SYSTEM TOOK A COORDINATED APPROACH IN ADDRESSING EBOLA VIRAL DISEASE

Criticisms of federal public health entities,⁶⁵ and CDC particularly,⁶⁶ for failures to prevent all cases of EVD from entering or proliferating in the United States were often grounded in the notion that our

neyland Measles Outbreak Continues to Spread, USA TODAY (Jan. 18, 2015, 3:14 PM), <http://www.usatoday.com/story/news/2015/01/18/disney-measles-spreads/21953767/> (The outbreak has the potential to develop into "one of the worst outbreaks since 1989."); *Complications of Measles*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/measles/about/complications.html> (last updated Nov. 3, 2014) (citing the measles fatality rate in the U.S. as 1–2 of every 1,000 children that contract the virus).

63. Letter from Dannel P. Malloy, Governor, State of Connecticut, to the Honorable Denise Merrill, Sec'y of the State, Martin J. Dunleavy, Clerk of the State House of Representatives, & Garey E. Coleman, Clerk of the State Senate (Oct. 7, 2014), *available at* http://www.governor.ct.gov/malloy/lib/malloy/2014.10.07_Declaration_of_Public_Health_Emergency.pdf.

64. Carol E. Lee, *Obama to Name Ron Klain as Ebola Czar*, WALL ST. J., <http://www.wsj.com/articles/obama-to-name-ron-klain-as-ebola-czar-1413557184> (last updated Oct. 17, 2014, 3:32 PM).

65. Michael Grunwald, *How a 'Czar' Fights a Disease*, POLITICO MAG. (Jan. 19, 2015), http://www.politico.com/magazine/story/2015/01/ron-klain-what-the-white-house-did-to-fight-ebola-114325_Page2.html#_VMF4xcY7VUQ; Ali Elkin, *Jeb Bush Criticizes Obama on Ebola, ISIS, Life in General*, BLOOMBERG POLITICS (Oct. 29, 2014, 7:23 AM), <http://www.bloomberg.com/politics/articles/2014-10-29/jeb-bush-criticizes-obama-on-ebola-isis-life-in-general>; Andrew Siddens, *Panel's G.O.P. Chairman Steps Up Criticism of Ebola Response*, N.Y. TIMES (Oct. 24, 2014), <http://www.nytimes.com/2014/10/25/us/politics/administrations-ebola-response-draws-scrutiny-of-house-committee.html>; Rebecca Kaplan, *Could the U.S. Have Done More to Prevent Ebola from Arriving?*, CBS NEWS (Oct. 1, 2014, 6:00 AM), <http://www.cbsnews.com/news/ebola-could-the-u-s-have-done-more-to-prevent-it-from-arriving/>.

66. Ron Carucci, *What We Learned from CDC's Handling of Ebola*, CNBC (Nov. 3, 2014, 11:40 AM), <http://www.cnbc.com/id/102146727#>; Alex Berezow, *CDC Lost Its Ebola Gamble: Column*, USA TODAY (Oct. 24, 2014, 8:37 AM), <http://www.usatoday.com/story/opinion/2014/10/23/cdc-ebola-gamble-public-confidence-trust-truth-not-clueless-czar-column/17800077/>; Julie Steenhuisen, *U.S. CDC Head Criticized for Blaming 'Protocol Breach' as Nurse Gets Ebola*, REUTERS (Oct. 13, 2014, 7:07 PM), <http://www.reuters.com/article/2014/10/13/us-health-ebola-usa-nurse-idUSKCN01206820141013>.

national public health system is a well-coordinated, finely-tuned machine. It is not. In our federalist system of government, the powers to protect the public's health are split among varied levels of government. The federal government holds the purse strings for many public health funds, which it doles out largely to state and local governments which historically and contemporaneously hold specific public health powers are historically and contemporaneously vested in state and local governments.⁶⁷ They are the traditional protectors of the public's health in part because they possess the broadest range of public health powers.⁶⁸

The responsibility of assuring the nation that EVD was under control fell to federal public health entities like CDC, whose officials were relied on to educate the public on Ebola. Achieving this objective, however, is more so the responsibility of state and local governments working on the frontlines of public health preparedness in concert with doctors, nurses, emergency medical service providers, and other health care entities. Inherent weaknesses of our federalist public health system were revealed through the significant errors in the handling of patient, Thomas Eric Duncan, the first domestic case of EVD at Texas Health Presbyterian Hospital in Dallas, Texas. Multiple gaffes among public health and clinical personnel led to a host of harms, including the subsequent infection of two treating nurses with EVD at the hospital.⁶⁹ One of the nurses, Nina Pham, subsequently sued her employer alleging an array of public health offenses directly causing her harm.⁷⁰ Additional illustrations abound from other failures to apply known, efficacious best practices in emergency preparedness through state or local actors.⁷¹ Even when a nationally-coordinated, finely-tuned approach is needed to instill trust in the community against a perceived serious threat like Ebola, it may simply be unattainable.

67. JAMES G. HODGE, JR., PUBLIC HEALTH LAW IN A NUTSHELL 31–34 (2013); *see also* Barnini Chakraborty, *As Ebola Fears Spread, States Take Emergency Response into Their Own Hands*, FOX NEWS (Oct. 22, 2014), <http://www.foxnews.com/politics/2014/10/22/as-ebola-fears-spread-states-take-emergency-response-into-their-own-hands/> (“Not satisfied with the federal response, several states are taking the Ebola crisis into their own hands – tapping emergency funds in their budgets, launching treatment units and holding public hearings to stanch the spread of misinformation about the virus.”).

68. HODGE, *supra* note 67, at 33–34.

69. *Ebola: Hospital Mistakes Blamed for US Transmission*, BBC NEWS (Oct. 12, 2014, 4:33 PM), <http://www.bbc.com/news/world-us-canada-29590832>.

70. Jennifer Emily, *Free of Ebola, But Not Fear*, DALLAS MORNING NEWS (Feb. 28, 2015), <http://res.dallasnews.com/interactives.nina-pham/>.

71. James G. Hodge, Jr. et al., *Law, Medicine, and Public Health Preparedness: The Case of Ebola*, 130 PUB. HEALTH REPORTS 1, 1 (2015) (In addition to the initial release of Duncan, leading to the potential spread of EVD until his readmission, one of Duncan's nurses who contracted the disease was allowed to fly on a commercial airline despite the presence of possible symptoms. She was later diagnosed with EVD.).

MYTH V. FEDERAL QUARANTINE AND ISOLATION GUIDANCE
CONCERNING EBOLA MUST BE CLOSELY FOLLOWED BY
STATE AND LOCAL GOVERNMENTS

Perhaps one of the best examples of the limits of national coordination in EVD response arose from the national call for greater clarification on the use of quarantine and isolation powers.⁷² These ancient social distancing powers are often conflated, but are in fact distinct. Quarantine refers to the separation of persons exposed to communicable conditions (but not yet known to be infectious) from those not exposed or infectious.⁷³ Isolation refers to the separation of persons who are infectious with such a condition from those who are not.⁷⁴ Thus, a person who may have come into direct contact with bodily fluids of an EVD patient may be quarantined. An actual EVD patient, however, is isolated.

On October 24, 2014, Governors Cuomo (D. New York) and Christie (R. New Jersey) jointly declared their intent to mandatorily quarantine, for up to three weeks, any HCW returning to their respective jurisdictions from treating EVD patients in West Africa.⁷⁵ Those determined to have contracted EVD would be isolated and treated. Imposing a limited quarantine on all returning HCWs from Ebola hot zones may seem wise in the interests of protecting the public's health, but it exceeded best practices underlying the use of these powers. As discussed further below, typically quarantine is justified only when one's exposure to a contagious condition is coupled with other indicators of potential infection (e.g., fever, nausea, or known instances of unprotected and direct exposure to EVD). Absent these or other known factors, the wholesale quarantine of HCWs lacks a sufficient public health basis.

After the joint announcement in New York and New Jersey, CDC quickly disseminated its own guidance on the appropriate risk categories and corresponding interventions to justify specific quarantine and isolation measures.⁷⁶ Providing uniform national guidance would allegedly deter deleterious public health practices among state and local governments. In reality, CDC's guidance was considered and summarily rejected in part by nearly a dozen states, including populous states like California, Florida, New York, and Texas, which set divergent criteria or thresholds for the application of quarantine and isolation in

72. JARED P. COLE, CONG. RESEARCH SERV., RL33201, FEDERAL AND STATE QUARANTINE AND ISOLATION AUTHORITY (2014), available at <https://www.fas.org/sgp/crs/homsec/RL33201.pdf>.

73. HODGE, *supra* note 67, at 94.

74. Lawrence O. Gostin & Benjamin E. Berkman, *Pandemic Influenza: Ethics, Law, and the Public's Health*, 59 ADMIN. L. REV. 121, 171 (2007).

75. Cuomo & Christie Press Release, *supra* note 8.

76. *Epidemiologic Risk Factors to Consider When Evaluating a Person for Exposure to Ebola Virus*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vhf/ebola/exposure/risk-factors-when-evaluating-person-for-exposure.html> (last updated Nov. 28, 2014).

their jurisdictions.⁷⁷ Media and others questioned how states could fail to follow CDC guidance.⁷⁸ It is quite easy. Outside the context of a federally-declared emergency or the existence of a federal funding stream for which state adherence is tied to federal conditions via the constitutional spending powers,⁷⁹ state public health authorities generally do not have to follow CDC guidance. They are entitled to go their own way consistent with their sovereign public health legal powers, as demonstrated further in the myth below.

MYTH VI. MANDATORY QUARANTINE OF HEALTH CARE WORKERS FROM EBOLA “HOT ZONES” IS LAWFUL AND ESSENTIAL

On Friday, October 24, 2014, New Jersey Governor Christie determined that nurse Kaci Hickox must be quarantined.⁸⁰ Hickox had tested positive with an elevated fever via screening at the Newark International Airport where she returned from multiple weeks abroad treating EVD patients in Sierra Leone. In collaboration with state public health authorities and amidst a developing media circus just about a week prior to his re-election, Governor Christie ordered Hickox to remain in a hastily-built tent located adjacent to University Hospital in Newark. For over 60 hours, Hickox was physically separated from family, friends, and her lawyer behind a canvas tent with plastic windows while being monitored regularly for additional signs of Ebola infection.⁸¹

When no additional symptoms surfaced and she threatened to sue, Hickox was allowed on Monday, October 27, to return to her residence in her native state of Maine which she shared with her boyfriend.⁸²

77. JAMES G. HODGE, JR., NETWORK PUB. HEALTH L., EMERGENCY LEGAL PREPAREDNESS CONCERNING EBOLA: A PRIMER (2014), available at https://www.networkforphl.org/_asset/dzf8u4/Ebola-Outbreak-2014—Network-Overview.pdf (these states include CA, FL, GA, IL, IN, LA, ME, MD, NH, NJ, NY, OH, TX, VA).

78. Philip M. Boffey, *C.D.C. Ebola Guidelines Aren't Good Enough for Some States*, N.Y. TIMES (Oct. 30, 2014, 4:35 PM), <http://takingnote.blogs.nytimes.com/2014/10/30/c-d-c-ebola-guidelines-arent-good-enough-for-some-states/> (noting that while CDC “hoped that its rules would head off the confusion resulting from separate state-by-state policies” eleven states still released diverging guidelines within one week of the release of the CDC guidance); Toluse Olorunnipa & Angela Greiling Keane, *White House Says States Can't be Forced to Follow CDC*, ILL. NEWS, <http://ilinnnews.com/white-house-says-states-cant-be-forced-to-follow-cdc/> (last visited Feb. 23, 2015).

79. HODGE, *supra* note 67, at 111–14; Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012) (holding that a statutory provision providing DHHS Secretary authority to penalize States choosing not to participate in the Act's expansion of Medicaid program exceeded Congress' spending power); South Dakota v. Dole, 483 U.S. 203 (1987) (holding that a statute conditioning receipt of select highway funds on adoption of minimum drinking age is valid use of Congress' spending power).

80. Anemona Hartocollis & Emma G. Fitzsimmons, *Tested Negative for Ebola, Nurse Criticizes Her Quarantine*, N.Y. TIMES (Oct. 25, 2014), http://www.nytimes.com/2014/10/26/nyregion/nurse-in-newark-tests-negative-for-ebola.html?_r=0.

81. *Id.*

82. Liz Robbins, Michael Barbaro & Marc Santora, *Unapologetic, Christie Frees Nurse From Ebola Quarantine*, N.Y. TIMES (Oct. 27, 2014), <http://www.nytimes.com/2014/10/28/nyregion/nurse-in-newark-to-be-allowed-to-finish-ebola-quarantine-at-home-christie-says.html>.

Health and law enforcement officials closely monitored them both. Maine Governor Paul LePage and Health Commissioner Mary Mayhew promptly attempted to impose a mandatory 21-day “home quarantine” court order⁸³ on Hickox after she and her boyfriend left the house to take a bike ride.⁸⁴ The proclaimed basis for the order extended from the significant need to protect the community’s health from the specter of Ebola tied to Hickox and other HCWs. After a similarly-situated HCW, Dr. Craig Spencer, was determined to be EVD positive just 24 hours after roaming around varied destinations in New York City,⁸⁵ Maine’s limited quarantine against Hickox seemed necessary and legitimate from a public health perspective.

The only problem is that use of quarantine powers in this case was unlawful. On October 31, 2013, a district court judge found in *State of Maine Department of Health and Human Services v. Hickox*⁸⁶ that the State lacked “clear and convincing evidence” that Hickox posed sufficient risks to the community to support its mandatory quarantine.⁸⁷ Hickox’s initial high temperature reading at the airport proved to be an anomaly. She evinced no further symptoms of EVD from that moment forward. Lacking any additional proof of harm related to Hickox, who promised public health authorities to continue to self-monitor her condition until the end of the incubation period, her quarantine was unnecessary and thus unlawful.⁸⁸

83. Mayhew v. Hickox, No. FORDC-CV-2014-36, 2014 U.S. Dist. (D. Maine Oct. 31, 2014) (temporary order), available at http://www.courts.maine.gov/news_reference/high_profile/hickox/temporary_order.pdf [hereinafter Mayhew Temporary Order].

84. Jennifer Levitz, *Nurse Defies Ebola Quarantine in Maine*, WALL ST. J. (last updated Oct. 30, 2014, 7:13 PM), <http://www.wsj.com/articles/nurse-defies-ebola-quarantine-in-maine-takes-a-bike-ride-1414678589>.

85. Faith Karimi, *From Guinea to the U.S.: Timeline of First Ebola Patient in New York City*, CNN (Oct. 25, 2014, 1:00 AM), <http://www.cnn.com/2014/10/24/health/new-york-ebola-timeline/>; see also Grunwald, *supra* note 65 (“The case of Dr. Craig Spencer in New York was a big learning moment for people. You had someone come back, an American citizen doing heroic work in West Africa. He had Ebola. He came back to New York, he rode the subway, he went bowling, he ate out, he spent time with his fiancée and friends. He was quickly identified and treated superbly at Bellevue Hospital. And the bottom line was: No one but Craig Spencer got Ebola. Not the people who rode the subway with him, not the people who bowled with him, not his friends, not the courageous doctors and nurses who treated him. Nobody got Ebola.”).

86. Mayhew Temporary Order, *supra* note 83, at 2.

87. *Id.*

88. *Contra* In re Washington, 735 N.W.2d 111, 114 (Wis. 2007). A homeless woman with TB who failed to adhere to directly-observed therapy was jailed because she posed a threat to the public’s health. The Wisconsin Supreme Court upheld her confinement because the jail was “a place where proper care and treatment [would] be provided [and] the spread of disease [would] be prevented,” with no less restrictive means available. *Id.*; see also City of New York v. Antonette, 630 N.Y.S.2d 1008 (N.Y. Sup. Ct. 1995) (allowing forcible detention of person with active TB in hospital based on clear and convincing evidence that detention was necessary); HODGE, *supra* note 67, at 85–86.

MYTH VII. AIRPORT SCREENING PRACTICES ARE EFFICACIOUS IN
DETECTING AND PREVENTING IMPORTATION OF EBOLA CASES

The Hickox case leads nicely into another myth of public health legal preparedness for EVD surrounding the use of airport screening practices. Facing political pressure from Congress and intense media scrutiny, the federal government announced on October 8, 2014 that enhanced screening for EVD would be conducted at five domestic airports that receive nearly all of the passengers arriving from Sierra Leone, Liberia, and Guinea (albeit indirectly following other international flights).⁸⁹ Additional countries like Mali were later added (and then removed) from the list.⁹⁰ Even though these passengers were screened for EVD just hours before prior to getting on board their destination flights from West Africa, federal agents escorted these passengers on arrival in the United States to a designated area, took their temperature with a noncontact thermometer, observed them for other symptoms, and inquired about their health and exposure history.⁹¹ Anyone fitting a risk profile, like Hickox, was subjected to further evaluation by CDC health officers who eventually handed thousands of high risk passengers off to state or local public health agents for additional monitoring for up to three weeks (depending on the length of the passengers' stay).⁹²

Airport entry screening for EVD represented the first time in modern recollection that fever monitoring was used nationally to detect and

89. *Enhanced Ebola Screening to Start at Five U.S. Airports for All People Entering U.S. from Ebola-Affected Countries*, U.S. DEP'T OF HOMELAND SEC. (Oct. 8, 2014), <http://www.dhs.gov/news/2014/10/08/enhanced-ebola-screening-start-five-us-airports-all-people-entering-us-ebola>. Additional screening practices at U.S. borders were also conducted as part of this strategy to detect and deter incoming cases. *See, e.g.*, Murphy Woodhouse, *13 African Travelers Screened for Ebola at Nogales Ports*, NOGALES INT'L (Jan. 8, 2015, 4:27 PM), http://www.nogalesinternational.com/news/african-travelers-screened-for-ebola-at-nogales-ports/article_da6e8aee-978d-11e4-a821-579889ab2466.html (noting that additional Ebola screening at land ports is required if federal Border Patrol officers have "reason to believe (a person) has been present in Liberia, Sierra Leone or Guinea in the preceding 21 days").

90. *Enhanced Airport Entry Screening to End for Travelers from Mali to the United States*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/media/releases/2015/p0105-enhanced-airport-screening.html> (last updated Jan. 5, 2015).

91. *Fact Sheet: Screening and Monitoring Travelers to Prevent the Spread of Ebola*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vhf/ebola/travelers/ebola-screening-factsheet.html> (last updated Jan. 6, 2015).

92. Grunwald, *supra* note 65 ("[The federal government] pursued something we've never done before, which is to identify who starts traveling there, and when they come to America, the customs officer who processes their passport has identified them in advance, is looking for that person, sends them to a screening facility that we've got at the five airports where we funnel all these passengers. Then, CDC experts take their temperatures, identify if they have any risks [and what] . . . their activities have been in West Africa. They assign each individual a unique identifying number, hand them a 30-day cell phone, and then we communicate that information directly to [state or local] public health authorities, so we can track that person every day for the first 21 days in the county, make sure we get their temperature twice a day, find them if we need to find them and get them quickly to the right hospital if they turn out to be sick. And that monitoring and tracking system has been the backbone of what's protected the country from further Ebola cases.").

deter persons arriving to the United States with an infectious condition.⁹³ While purportedly lawful,⁹⁴ these screening procedures are also wasteful, specious, and harmful to the public's health. They are wasteful in the sense that no known American patient with Ebola to date has been identified through these practices.⁹⁵ They are specious to the extent they do not materially improve border security against Ebola because they are prone to false positives (e.g., Hickox) and evasion (e.g., Duncan lied about his exposure to EVD during his exit screening in Liberia).⁹⁶ Such screening practices have the potential to harm the public's health by driving EVD cases underground or across borders in ways that cannot be detected.⁹⁷

MYTH VIII. EXPERIMENTAL TESTS, VACCINES, AND DRUGS ARE LAWFULLY USED TO COMBAT EBOLA VIRAL DISEASE

As a global leader in pharmaceutical research and development, surely some U.S. company has developed a test, vaccine, or drug that is efficacious and available to detect, deter, or treat EVD. This may be true, but the extent to which these experimental resources may be authorized for use is more myth than fact. There are many lawful avenues for approval of experimental tests, vaccines, and drugs through FDA. Yet significant legal hoops and limitations on the use of these options restrict the numbers of tests, vaccines, and drugs that may pro-

93. Sabrina Tavernise, *Newly Vigilant, U.S. Will Screen Fliers for Ebola*, N.Y. Times (Oct. 8, 2014), <http://www.nytimes.com/2014/10/09/us/newly-vigilant-us-is-to-screen-fliers-for-ebola.html>.

94. Federal authorities are statutorily authorized to screen passengers for a series of infectious diseases, including EVD, via the Public Health Service Act, 42 U.S.C. § 264, and the Aviation and Transportation Security Act, 49 U.S.C. § 44901. However, if screening practices are demonstrated to lack efficacy related to furthering any legitimate public health objective, they may be challenged as an unconstitutional invasion of bodily privacy in violation of the Fourth Amendment protections against unreasonable searches (at least as applied to U.S. citizens). See *Skinner v. Ry. Labor Execs. Ass'n*, 489 U.S. 602 (1989) (holding that alcohol and drug testing of employees is reasonable and consistent with the need to protect public safety); *Glover v. Eastern Neb. Cmty. Office of Retardation*, 867 F.2d 461 (8th Cir. 1989) (holding that employee testing for Hepatitis B and HIV did not unconstitutionally invade privacy because the risk to patients was insufficient); *City of Ontario, Cal. v. Quon*, 560 U.S. 746, 763(2010) (stating the Court's continued refusal "to declare that only the 'least intrusive' search practicable can be reasonable under the Fourth Amendment"). No challenge to federal screening practices for EVD has been filed in any federal or state court based on a search for relevant cases as of January 21, 2015.

95. Szabo, *supra* note 15.

96. Norimitsu Onishi & Marc Santora, *Ebola Patient in Dallas Lied on Screening Form, Liberian Airport Official Says*, N.Y. TIMES (Oct. 2, 2014), <http://www.nytimes.com/2014/10/03/world/africa/dallas-ebola-patient-thomas-duncan-airport-screening.html>; *Non-Contact Temperature Measurement Devices: Considerations for Use in Port of Entry Screening Activities*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 22, 2014), available at <http://wwwnc.cdc.gov/travel/pdf/ebola-non-contact-temperature-measurement-guidance.pdf>.

97. Sharon Begley, *Prescription for Avoiding Ebola Airport Screening: Ibuprofen*, REUTERS (Oct. 3, 2014, 1:17 AM), <http://www.reuters.com/article/2014/10/03/us-health-ebola-screening-idUSKCN0HS09J20141003> ("People who contract Ebola in West Africa can get through airport screenings and onto a plane with a lie [on airport questionnaires] and a lot of ibuprofen [to reduce fever]. . .").

vide meaningful benefits, notwithstanding sometimes considerable risks underlying their use.

While FDA approved several diagnostic tests and drugs to detect or treat EVD, these authorizations are variant and highly-limited. To date, FDA has not approved any vaccines or drugs that are known to prevent or efficaciously treat EVD.⁹⁸ Several investigational products were approved under FDA's emergency use authorization ("EUA") powers via the Federal Food, Drug, and Cosmetic Act.⁹⁹ For example, FDA issued several EUAs for diagnostic tests (otherwise unapproved for general use) to detect EVD patients with greater speed and specificity.¹⁰⁰ Each EUA details specific limitations on the type of specimens to be tested (e.g. blood, plasma, or urine), the population intended for use (e.g. "at risk" or exposed individuals), and the types of instruments or qualified laboratories capable of handling the collected specimens.¹⁰¹

FDA can also authorize the use of an emergency investigational new drug ("IND") to treat individuals when manufacturers or medical teams seek and obtain approval. In response to EVD, for example, FDA granted IND applications for drugs like TKM-Ebola¹⁰² and Brincidofovir,¹⁰³ aimed at treating Ebola symptoms and a potential vaccine to prevent post-exposure spread of EVD.¹⁰⁴ Similar to an EUA, IND approval does not authorize general use. Additional applications related to other experimental drugs may be pending or denied. Since FDA does not disclose the existence of an IND application unless it has been previously publicized,¹⁰⁵ reliable data on the numbers of unapproved applications are unavailable.¹⁰⁶

Facts surrounding ZMappTM, an experimental and expensive drug¹⁰⁷ that emerged as a treatment for EVD, are illustrative albeit sketchy. Dr. Kent Brantly was one of the first American doctors working in West Africa to contract EVD and be transported back to the states for life-saving treatment in August 2014. He purportedly received doses of ZMapp in West Africa prior to his hospitalization at Emory University

98. *Ebola Response Updates from FDA*, *supra* note 10.

99. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 (2013).

100. *Ebola Response Updates from FDA*, *supra* note 10.

101. *Id.*

102. *About Investigational TKM-Ebola Therapeutic*, TEKmira, <http://www.tekmira.com/pipeline/tkm-ebola.php> (last visited Jan. 15, 2015).

103. Press Release, Chimerix Announces Emergency Investigational New Drug Applications for Brincidofovir Authorized by FDA for Patients With Ebola Virus Disease (Oct. 6, 2014), *available at* <http://ir.chimerix.com/releasedetail.cfm?releaseid=874647>.

104. *Ebola Virus Disease (EVD) Information for Clinicians in U.S. Healthcare Settings*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vhf/ebola/hcp/clinician-information-us-healthcare-settings.html> (last updated Jan. 13, 2015).

105. 21 C.F.R. § 312.130.

106. 21 C.F.R. § 314.430.

107. Brent McClusky, *Tobacco Plants Hold Key To Ebola Virus Cure ZMapp*, THE FIX (Oct. 10, 2014), <http://www.thefix.com/content/tobacco-plants-hold-key-ebola-cure> ("It costs up to \$100,000 to treat a single patient [with ZMapp] . . .").

Hospital.¹⁰⁸ Whether the administration of this drug was directly approved by FDA is still something of a mystery.¹⁰⁹ Though experts surmise that FDA must have been involved in allowing the use of ZMapp™, Brantly received his dose in Liberia,¹¹⁰ where FDA's authority to regulate exported, experimental (or other) drugs is lacking.¹¹¹ The supply of ZMapp™, which was donated by its manufacturer to patients at no cost, was reportedly exhausted later that same month.¹¹² Months later, however, an additional HCW who contracted EVD working abroad, Dr. Martin Salia, received a dose of the drug in Nebraska in November 2014, but later died.¹¹³ Whether FDA directly authorized or approved the domestic administration of ZMapp™ to Dr. Malia or other patients is not clear although no federal actions have been filed against entities or HCWs who may have administered it to patients in

108. Dr. Sanjay Gupta & Danielle Dellorto, *Experimental Drug Likely Saved Ebola Patients*, CNN (Aug. 5, 2014, 8:22 PM), <http://www.cnn.com/2014/08/04/health/experimental-ebola-serum/>.

109. Staci Kearney, *Ebola Epidemic Shines Light on Expanded Access*, AGEIS (Nov. 24, 2014), <http://aegiscreative.com/blog/ebola-epidemic-shines-light-expanded-access/> ("FDA will not say whether the use of ZMapp . . . was the result of an emergency-use authorization, but some FDA involvement seems likely."); *Status Update on ZMapp*, MAPP BIOPHARMACEUTICAL (Oct. 9, 2014), <http://www.mappbio.com/10-update.pdf> ("ZMapp™ was available for compassionate use. . . . On September 2, Mapp Pharmaceutical received a contract from the U.S. government through the Biomedical Advanced Research and Development Authority (BARDA) to fund continued manufacture and clinical development of ZMapp™ in accordance with FDA rules and regulations. Clinical investigational lots manufactured under this contract will be used in Phase 1-2 clinical studies evaluating the safety and efficacy of ZMapp™.").

110. Assoc. Press, *FDA Lifts Hold on Experimental Ebola Drug*, N.Y. TIMES (Aug. 7, 2014, 6:06 PM), <http://www.nytimes.com/aponline/2014/08/07/us/politics/ap-us-ebola-drug-fda-hold.html>.

111. *Exporting Drugs Does Not Need to Be Mission Impossible*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm314118.htm> (last updated Aug. 2, 2012) ("Companies may export unapproved drugs to virtually anywhere. [But], there are requirements that must be met. Unapproved new human drugs can be exported when it complies with the laws of the importing country and has marketing authorization in certain other countries. . . . When an unapproved drug is first exported, the exporter must notify FDA and continue to maintain adequate records."). See also *Guidance for Industry - Exports Under the FDA Export Reform and Enhancement Act of 1996*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125799.htm#summary> (last updated Aug. 5, 2014) (explaining that under the Federal Food, Drug, and Cosmetics Act § 801(c)(1), "a food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded [and therefore complies with general FDA export requirements] if the article: [1] Accords to the specifications of the foreign purchaser; [2] Is not in conflict with the laws of the country to which it is intended for export; [3] Is labeled on the outside of the shipping package that it is intended for export; and [4] Is not sold or offered for sale in domestic commerce").

112. Press Release, Mapp Biopharmaceutical (Aug. 12, 2014), available at <https://web.archive.org/web/20140812203657/http://www.mappbio.com/>.

113. Abby Phillip & Emily Wax-Thibodeaux, *'Critical Threshold': The Failed Race to Save the Life of Ebola-Stricken Doctor Martin Salia*, WASH. POST (Nov. 17, 2014), <http://www.washingtonpost.com/news/post-nation/wp/2014/11/17/martin-salia-ebola-stricken-surgeon-from-sierra-leone-dies-in-nebraska-hospital/>.

the United States,¹¹⁴ suggesting FDA may have implicitly approved the use of ZMapp™ in this limited circumstance.

CONCLUSION

As the Ebola outbreak in West Africa continues with known cases exceeding 21,000, and deaths numbering nearly 8,500,¹¹⁵ limiting the spread of cases of EVD globally and domestically is an international goal that may be months or years in the making. Against the backdrop of EVD or other emerging infectious disease threats is the need to separate myths from realities underlying legal preparedness and response. Primary drivers for some of these myths include political whimsies, media pressures, insufficient governance structures, legal misunderstandings, and overzealous public officials and health authorities. In the end, this toxic mix of public health measures may be grounded more so in fervor to respond than efficacy of results or legality to act. From a public health perspective, only those interventions known to prevent the spread of infectious disease threats without significant, collateral public health repercussions may be legally sustained.¹¹⁶

114. Though there is a lack of evidence that FDA sought sanctions against entities or HCWs for their unlawful administration of ZMapp™, FDA has issued at least six warning letters to firms marketing products that purport to prevent, treat, or cure EVD infection. *Ebola Response Updates from FDA*, *supra* note 10.

115. EBOLA RESPONSE ROADMAP SITUATION REPORT UPDATE, WORLD HEALTH ORG. (Jan. 14, 2015), *available at* http://apps.who.int/iris/bitstream/10665/148237/2/roadmapsitrepre_14Jan2015_eng.pdf?ua=1.

116. James G. Hodge, Jr., *Global and Domestic Legal Preparedness and Response: 2014 Ebola Outbreak*, 10 J. DISASTER MED. & PUB. HEALTH PREPAREDNESS 1 (2014).

